In the United States Court of Federal Claims

No. 16-994V
Filed Under Seal: September 17, 2019
Reissued: October 29, 2019[*]

NICHOLAS ZUMWALT, *parent of L.Z., a minor*,	)	
Petitioner,	)	National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa–1 to –34 (2012); Tetanus-Diphtheria Acellular Pertussis Vaccine; Haemophilus Influenza Type B; Pneumococcal; Rotavirus; Hepatitis B; Inactivated Poliovirus Vaccine; Seizure; Encephalopathy; *Althen* Prong One; Treating Physician; *Althen* Prong Two.
v.	)	
SECRETARY OF HEALTH AND HUMAN SERVICES,	)	
Respondent.	)	

Andrew D. Downing, Esq., Phoenix, AZ, for petitioner.

Ryan D. Pyles, Trial Attorney, Torts Branch, Civil Division, *Joseph H. Hunt*, Assistant Attorney General, Civil Division, *C. Salvatore D'Alessio,* Acting Director, *Catherine E. Reeves*, Deputy Director, *Gabrielle M. Fielding*, Assistant Director, Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

MEMORANDUM OPINION AND ORDER

GRIGGSBY, Judge

I. INTRODUCTION

Petitioner, Nicholas Zumwalt, seeks review of the special master's March 21, 2019, decision (the "March 21, 2019, Decision") denying his claim for compensation on behalf of his minor son, L.Z., under the National Childhood Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. §

[*] This Memorandum Opinion and Order was originally filed under seal on September 17, 2019 (ECF No. 78). The parties were given an opportunity to advise the Court of their views with respect to what information, if any, should be redacted from the Memorandum Opinion and Order. The parties filed a joint status report on October 29, 2019 (ECF No. 83) stating that no redactions are necessary. And so, the Court is reissuing its Memorandum Opinion and Order, dated September 17, 2019.

300aa–1 to –34 (2012). For the reasons set forth below, the Court: (1) **DENIES** petitioner's motion for review and (2) **SUSTAINS** the decision of the special master.

II. FACTUAL AND PROCEDURAL BACKGROUND[1]

A. Factual Background

In this Vaccine Act matter, petitioner alleges that his son, L.Z., suffered a seizure disorder as a result of receiving the following vaccines on March 24, 2014: Haemophilus influenza type B ("HiB"); Pneumococcal ("Prevnar 13"); Rotavirus ("RotaTeq"); Diphtheria-tetanus-acellular pertussis ("DTaP"), Hepatitis B ("HBV"); and the Inactivated Poliovirus Vaccine ("IPV"). *See generally* Pet'r Pet. On March 21, 2019, the special master denied petitioner's claim for compensation under the Vaccine Act. *See generally* March 21, 2019, Decision.

1. Petitioner's Medical History

L.Z.'s medical history is discussed in detail in the special master's March 21, 2019, Decision and is summarized here. *See generally id.* L.Z. was born premature on September 24, 2013, and he was promptly admitted into the neonatal intensive care unit (the "NICU") due to a high heart rate. Pet'r Ex. 21, Part 1, at 4. At that time, L.Z. was diagnosed with supraventricular tachycardia and, after a successful cardioversion and medication, L.Z.'s heart rate lowered and remained at a normal rhythm during his six-day stay in the NICU. *Id.* at 4-5.

On October 24, 2013, L.Z. had his one-month well child visit with Dr. Geeta R. Silas, M.D., and he appeared healthy. Pet'r Ex. 3 at 72-75. The only issue identified during this visit was a rash near the opening of L.Z.'s urethra, for which medicine was prescribed. *Id.* at 74. In addition, Dr. Silas asked that L.Z. continue taking his heart medication. *Id.* at 75. On November 25, 2013, L.Z. had his two-month well child visit with Dr. Silas and again he appeared healthy. *Id.* at 67. During this visit, L.Z. received his two-month vaccinations without issue and Dr. Silas recommended that L.Z. continue taking heart medication. *Id.* at 70-71.

[1] The facts recounted in this Memorandum Opinion and Order are taken from the petitioner's petition ("Pet'r Pet."); petitioner's motion for review ("Pet'r Mot. for Rev."); petitioner's memorandum in support of his motion for review ("Pet'r Mem."); petitioner's exhibits ("Pet'r Ex."); the entitlement hearing transcript ("Tr."); and the special master's March 21, 2019, Decision ("March 21, 2019, Decision"). Except where otherwise noted, the facts recited herein are undisputed.

On January 24, 2014, during his four-month well child visit, L.Z.'s condition presented a few concerns for Dr. Silas. Pet'r Ex. 3 at 61-66. Specifically, L.Z.'s social interactions and eye contact were inconsistent for his age. *Id.* at 61. L.Z. also failed four of the twelve developmental milestone tests—including visually tracking objects beyond the midline, bringing a toy to his mouth, orienting himself to a voice, and laughing out loud. *Id.* at 62. L.Z. received his four-month vaccinations, again without issue, during this visit. *Id.* at 64-65.

On March 24, 2014, L.Z. had his six-month well child visit with Dr. Silas. Pet'r Ex. 3 at 55-59. During this visit, L.Z. failed two of the twelve developmental milestone tests—which include reaching for and raking at objects and transferring objects from hand to hand. *Id.* at 56. While the majority of the findings from L.Z.'s physical examination were normal, Dr. Silas expressed concerns regarding L.Z.'s eye contact, head lag, increased tone in his lower extremities, and tight hands and fists. *Id.* at 57. Dr. Silas also noted some concern regarding L.Z.'s neurological and psychiatric systems and observed that there was "inappropriate interaction." *Id.* Dr. Silas also observed that L.Z. was inconsolable and there was a "SLIGHT DELAY!!" *Id.* Due to these concerns, Dr. Silas referred L.Z. to Laura Taylor, DO, who specializes in pediatric development at the Tulsa Sunshine Center for physical therapy, evaluation and treatment. *Id.* at 59.

During his six-month well child visit, L.Z. also received his six-month vaccinations, which included: Haemophilus influenza type B ("HiB"); Pneumococcal ("Prevnar 13"); Rotavirus ("RotaTeq"); Diphtheria-tetanus-acellular pertussis ("DTaP"), Hepatitis B ("HBV"); and the Inactivated Poliovirus Vaccine, Pediarix ("IPV"). *Id.* at 58. L.Z. did not experience any immediate reactions after receiving these vaccines. Tr. at 7:18-7:24.

On March 28, 2014, L.Z. was assessed for potential developmental delays at the Tulsa SoonerStart Early Intervention office. Pet'r Ex. 12. Due to significant delays in his "adaptive, fine motor and cognitive skills," the evaluators found that L.Z. qualified for the SoonerStart Early Intervention Program. *Id.* at 3. In addition, the evaluators determined that L.Z. did not pass the vision screening and that L.Z. needed a follow up regarding his hearing. *Id.* at 1.

On the evening of April 1, 2014, petitioner woke L.Z. from his nap and L.Z. "appeared pale, lethargic, and unresponsive." Pet'r Ex. 1 at ¶ 4. And so, petitioner took L.Z. to the emergency room at St. Francis Hospital in Tulsa, Oklahoma for an evaluation. *Id.* While in the

pediatric emergency room, L.Z. reportedly experienced clonic activity and he was given medicine and the movement resolved. Pet'r Ex. 11, Part 1, at 45. The physician at the hospital ordered a computerized tomography ("CT") scan of L.Z.'s head. Pet'r Ex. 22, Part 10, at 2464. A CT scan was completed and no acute intracranial abnormalities were found at that time. *Id.*

On April 2, 2014, L.Z. was admitted to St. Francis's general pediatric floor in status epilepticus, with right lip smacking and right clonic arm movement and a low-grade fever of 36.8 degrees celsius. *Id.* at 2522. Thereafter, L.Z. was transferred to the Pediatric Intensive Care Unit (the "PICU") at the hospital. *Id.* A CT scan taken of L.Z.'s head was abnormal and showed evidence of asymmetry with a possible structural defect on the left frontoparietal head region. Pet'r Ex. 11, Part 1, at 45. A continuous electroencephalogram ("EEG") study was abnormal, reflecting left hemispheric slowing with periodic lateralizing epileptiform activity over the left, but without seizures. *Id.*

L.Z.'s magnetic resonance imaging ("MRI") taken on April 4, 2014, "showed no evidence of a structural, infectious or hemorrhagic/ischemic injury and reportedly [was] completely normal." *Id.* at 35, 47. In addition, L.Z.'s initial lumbar puncture showed cerebrospinal fluid pleocytosis of 256 white blood cells, but, a repeat lumbar puncture showed decreased pleocytosis of 14 white blood cells. Pet'r Ex. 22, Part 6 at 1339. And so, on April 17, 2014, L.Z. was discharged from the hospital and prescribed phenobarbital, prevacid, acyclovir, and diastat for seizures greater than five minutes. Pet'r Ex. 22, Part 8, at 1923, 1926.

On the evening of April 26, 2014, L.Z.'s parents observed that L.Z. began to act strangely, by not making eye contact and not interacting. Pet'r Ex. 22, Part 6, at 1339. On April 27, 2014, L.Z. suffered a seizure and he returned to St. Francis Hospital. *Id.* at 1319. While hospitalized, L.Z. was placed on various medications, but his seizing continued. *Id.* at 1319-20. And so, on April 29, 2014, L.Z. was placed into a medically induced coma. *Id.* at 1341.

An MRI scan taken on May 6, 2014, showed that the volume of L.Z.'s brain had decreased since April 4, 2014. Pet'r Ex. 22, Part 7, at 1677. And so, L.Z. was transferred to Cook Children's Hospital located in Fort Worth, Texas. Pet'r Ex. 13, Part 2, at 426.

On May 14, 2014, L.Z. returned to St. Francis Hospital and while hospitalized there a 24-hour EEG was conducted on May 25-26, 2014, which showed frequent electrographic seizures, generalized background slowing with right hemispheric asymmetric slowing, and frequent

multifocal epileptiform discharges. Pet'r Ex. 22, Part 6, at 1163-64; 1182. Dr. David Siegler, M.D., a pediatric neurologist, deemed the results of L.Z.'s EEG to be consistent with a diagnosis of infantile epileptic encephalopathy. *Id.* at 1164. L.Z.'s medical records from this time period do not identify the vaccines that L.Z. received on March 24, 2014, to be potential causes of his symptoms. *See generally* Pet'r Ex. 22, Part 6.

In June 2014, Dr. Siegler informed L.Z.'s family that the etiology of L.Z.'s condition may never be ascertained. Pet'r Ex. 11, Part 1 at 35. During L.Z.'s hospitalization at the Cook Children's Hospital, L.Z.'s medical team speculated that he may have Alpers' disease or a genetic disorder related to a genetic mutation. Pet'r Ex. 11, Part 2 at 170; Pet'r Ex. 22, Part 6 at 1180. But, L.Z.'s test results were ultimately negative for those conditions. Pet'r Ex. 22, Part 1 at 89. The results of an epilepsy screening and test for autoimmune condition were also negative. *Id.* at 32-33; *see also* Pet'r Ex. 10 at 1-2.

In January 2015, L.Z. was referred to neurologist Dr. Cynthia Keator, M.D., who suggested that febrile inducted refractory status epilepticus ("FIRES") was the most accurate description of L.Z.'s condition. Pet'r Ex. 11, Part 2, at 136-142. But, Dr. Keator noted that the actual etiology was still unknown. *Id.* at 140. And so, Dr. Keator concluded that L.Z. likely had FIRES of an unknown origin, but she also observed that there was a possibility that L.Z.'s condition may be due to Aicardi-Goutières syndrome. Pet'r Ex. 13, Part 1, at 156.

In July 2015, L.Z. was tested for mitochondria, but the test revealed no mutation or disorder. Pet'r Ex. 13, Part 1, at 127. Thereafter, in October 2015, further genetic testing was conducted on L.Z. which revealed that L.Z. carries a variant in his UPDF3B gene which is linked to intellectual disability. *Id.* at 128-29. Dr. Jozef Gecz, a geneticist at the University of Adelaide in Australia, opined that this genetic variant was not likely the cause of L.Z.'s condition. Pet'r Ex. 25 at 1; *see also* Pet'r Ex. 48 at 4.

On September 10, 2016, after petitioner filed this matter, Dr. Siegler filed a report with the Vaccine Adverse Event Reporting System ("VAERS") attributing L.Z.'s seizures to his March 24, 2014, vaccinations. *See generally* Pet'r Ex. 17. In the VAERS report, Dr. Siegler described L.Z.'s post-vaccination adverse event as "intermittent periods of tonic activity of upper and lower extremities with clonus noted in the left lower extremity." *Id.* at 2. Dr. Siegler also

noted that the vaccinations resulted in both "[p]rolongation of [h]ospitalization" and "[p]ermanent [d]isability" in the VAERS report. *Id.* at 3.

To date, L.Z. remains significantly disabled, nonverbal and he has poor visual interactions. *See* Pet'r Ex. 63 at 8; *see also* Tr. at 19:23-21:6. And so, L.Z. requires constant care, suffers frequent seizures, is quadriplegic and he has experienced significant brain volume loss. Pet'r Ex. 1 at ¶¶ 11-12.

2. The Proceedings Before The Special Master

Petitioner commenced this Vaccine Act matter on August 12, 2016. *See generally* Pet'r Pet. Thereafter, petitioner submitted various medical records regarding L.Z.'s treatment and medical condition. *See generally* Pet'r Exs. Petitioner and the Secretary of Health and Human Services ("Secretary") have also submitted expert reports and medical literature to support their respective positions in this case. *See generally* Pet'r Exs. 26, 28-39, 41-46, 60-61, 64, 65; *see also* Resp't Exs. A-C, Ex. A at Tabs 1-15.

On September 10, 2016, L.Z.'s pediatric neurologist, Dr. Siegler, submitted a VAERS report attributing L.Z.'s seizures to his March 24, 2014, vaccinations. *See generally* Pet'r Ex. 17. On May 5, 2017, petitioner submitted a narrative report from Dr. David Siegler, which states that one or more of the vaccinations that L.Z. received on March 24, 2014, "triggered a neurologic inflammatory cascade resulting in the presentation of encephalitis with depressed level of consciousness, refractory status epilepticus and CSF pleocytosis and subsequent brain atrophy." Pet'r Ex. 24 at 16.

On July 18, 2017, petitioner submitted an expert report by Dr. Lawrence Steinman, M.D., a pediatric neurologist, in which Dr. Steinman opined that the components of the vaccines administered to L.Z. on March 24, 2014, are well-known to be associated with seizures. Pet'r Ex. 26 at 1, 8. On November 12, 2018, Dr. Steinman submitted a supplemental expert report clarifying that the pertussis toxin activity extends beyond five days, which was well through the time that L.Z.'s neurologic problems manifested. Pet'r Ex. 64. And so, Dr. Steinman opined

that the onset of L.Z.'s conditions relates to the activity of the pertussis toxin in the acellular DTaP vaccine. *Id.*[2]

On October 24, 2017, the Secretary filed an expert report by Dr. John Zempel, M.D., PhD, an expert in pediatric epilepsy and neurology. Resp't Ex. A at 1. In the report, Dr. Zempel opined that Dr. Steinman failed to cite to medical literature that indicates that L.Z.'s epilepsy was caused or associated with the vaccinations that he received on March 24, 2014. *Id.* at 10. In this regard, Dr. Zempel observed that cases of catastrophic epilepsy in infancy "will obviously in some cases have temporal overlap with the timing of vaccination." *Id.* Dr. Zempel also stated that "[t]he lack of an association between vaccination and catastrophic epilepsy is not merely my clinical opinion, but is reflected in the contemporaneous etiological differential diagnoses of the

[2] Petitioner's medical literature includes the following studies and reports: Institute of Medicine, National Academies of Sciences, Engineering, and Medicine, Considerations for Designing an Epidemiologic Study for Multiple Sclerosis and Other Neurologic Disorders in Pre and Post 9/11 Gulf War Veterans (2015); Lawrence Steinman, *A Journey in Science: The Privilege of Exploring the Brain and the Immune System*, 21 MOLECULAR MEDICINE 1047 (2016); Lawrence Steinman, *The Discovery of Natalizumab, A Potent Therapeutic for Multiple Sclerosis*, 199 J. OF CELL BIOLOGY 413 (2012); US Patent No. 5,000,952 (filed Aug. 2, 1988); Brady Huggett & Kathryn Paisner, *Top 20 Translational Researchers in 2012*, 31 NATURE BIOTECHNOLOGY 784 (2013); RotaTeq Package Insert; HIBAct Package Insert; Pentacel and Pediarix Package Inserts; W.J. Black et al., *ADP-ribosyltransferase Activity of Pertussis Toxin and Immunomodulation by Bordetella Pertussis*, 240 SCIENCE MAG. 656 (April 29, 1988); JR Oksenberg et al., *Multiple T and B Cell Epitopes in the S1 Subunit ("A"- monomer) of the Pertussis Toxin Molecule*, 143 J. OF IMMUNOLOGY 4227 (Dec. 15, 1989); Jorge R. Oksenberg et al., *MHC-Restricted Recognition of Immunogenic T Cell Epitopes of Pertussis Toxin Reveals Determinants in Man Distinct from the ADP-Ribosylase Active Site*, 168 J. EXP. MED. 1855 (Nov. 1988); Maria Teresa De Magistris et al., *Interaction of the Pertussis Toxin Peptide Containing Residues 30-42 with DR1 and the T-cell Receptors of 12 human T-cell clones*, 89 PROC. NAT'L ACAD. SCI. USA 2990 (Apr. 1992); Ling-yi Chi et al., *Poly(ADP-ribose) Signal in Seizures-Induced Neuron Death*, 71 MED. HYPOTHESES 283 (Feb. 2008); Weihai Ying et al., *Poly(ADP-ribose) Glycohydrolase Mediates Oxidative and Excitotoxic Neuronal Death*, 98 PROC. NAT'L ACAD. SCI. USA 12227 (Oct. 9, 2001); Sheng-jun Wang et al., *Poly(ADP-ribose) Polymerase Inhibitor is Neuroprotective in Epileptic Rat via Apoptosis-inducing Factor and Akt Signaling*, 18 MOLECULAR NEUROSCIENCE, NEUROREPORT 1285 (Aug. 6, 2007); Stephanie C. Eisenbarth et al., *Crucial Role for the Nalp3 Inflammasome in the Immunostimulatory Properties of Aluminium Adjuvants*, 453 NATURE 1122 (June 19, 2008); Roopa Bhat & Lawrence Steinman, *Innate and Adaptive Autoimmunity Directed to the Central Nervous System*, 64 NEURON REVIEW 123 (Oct. 15, 2009); S.R. Gomez et al., *ADP-ribosylation Activity in Pertussis Vaccines and its Relationship to the in vivo Histamine-Sensitisation Test*, 25 SCIENCEDIRECT 3311 (2007); Roopa Bhat and Lawrence Steinman, *Innate and Adaptive Autoimmunity Directed to the Central Nervous System*, 64 NEURON 123 (2009); National Organization for Rare Disorders, *Febrile Infection-Related Epilepsy Syndrome (FIRES)* (2018); John J. Munoz et al., *Biological Activities of Crystalline Pertussigen from Bordetella pertussis*, 33 INFECTION AND IMMUNITY 820 (Sept. 1981). *See* Pet'r Exs. 28-39, 41-46, 60-61, 65.

treating physicians." *Id.* at 10-11. And so, Dr. Zempel found no connection between vaccination and catastrophic epilepsy. *Id.*

On December 11, 2018, Dr. Zempel submitted a supplemental expert report in which he opined that Dr. Steinman "has not provided quality scientific, medical or epidemiological evidence that immunization with the inactivated pertussis vaccine is associated with seizures." Resp't Ex. C. at 1. And so, Dr. Zempel concluded that "[m]erely showing that the actual pertussis toxin . . . has prolonged biological effects does not establish that the inactivated pertussis vaccine has any causal relationship to a seizure that occurred eight days after vaccination." *Id.*[3]

On October 9, 2018, the special master held an entitlement hearing. *See generally* Tr. During the entitlement hearing, the following witnesses testified: Nicholas Zumwalt; Dr. David Siegler; Dr. Lawrence Steinman; and Dr. John Zempel. *See generally id.*

Specifically relevant to this matter, Dr. Steinman's expert testimony addressed how the RotaTeq or DTaP vaccines that L.Z. received on March 24, 2014, could have triggered the onset of L.Z.'s seizure disorder. Tr. at 81:23-85:4. In this regard, Dr. Steinman noted that the RotaTeq

[3] The Secretary's medical literature includes the following studies and reports: Gillian Rice et al., *Clinical and Molecular Phenotype of Aicardi-Goutières Syndrome*, 81 AM. J. HUM. GENET. 713 (Oct. 2007); Asako Takanohashi et al., *Elevation of proinflammatory cytokines in patients with Aicardi-Goutières syndrome*, 80 NEUROLOGY 997 (2013); Rani K. Singh et al., *Cognitive Outcomes in Febrile Infection-Related Epilepsy Syndrome Treated With the Ketogenic Diet*, 134 PEDIATRICS e1431 (Nov. 2014); Todd N. Wylie et al., *Enhanced virome sequencing using targeted sequence capture*, 25 GENOME RESEARCH 1910 (Sept. 2015); Carol A. Glaser et al., *Refractory Status Epilepticus in Suspect Encephalitis*, 9 NEUROCRIT. CARE 74 (Dec. 2007); Matthew J. Young and William C. Copeland, *Human mitochondrial DNA replication machinery and disease*, 38 CURR. OPIN. GENET. DEV. 52 (2016); J. Bonkowsky et al., *Deep Whole Genome Analysis (DWGA) for Effective Diagnosis and Gene Discovery in Early Infantile Epileptic Encephalopathy*, PROGRAM AND ABSTRACTS, CHILD NEUROLOGY SOCIETY S283 (2017); Anne T. Berg et al., *Early-Life Epilepsies and the Emerging Role of Genetic Testing*, 171(9) JAMA PEDIATR. 863 (Jul. 2017); Epi4K Consortium & Epilepsy Phenome/Genome Project, *De novo mutations in epileptic encephalopathies*, 501 NATURE 217 (Sept. 2013); Andreas van Baalen et al., *Febrile infection–related epilepsy syndrome (FIRES): A nonencephalitic encephalopathy in childhood*, 51(7) EPILEPSIA 1323 (2010); Andreas van Baalen et al., *Febrile Infection–Related Epilepsy Syndrome: Clinical Review and Hypotheses of Epileptogenesis*, 48 NEUROPEDIATRICS 5 (2017); Uri Kramer et al., *Febrile infection–related epilepsy syndrome (FIRES): Pathogenesis, treatment, and outcome A multicenter study on 77 children*, 52(11) EPILEPSIA 1956 (2011); Fatima Y. Ismail & Eric H. Kossoff, *AERRPS, DESC, NORSE, FIRES: Multi-labeling or distinct epileptic entities?*, 52(11) EPILEPSIA e185 (2011); Marianna S. Rivas-Coppola et al., *Chronological Evolution of Magnetic Resonance Imaging Findings in Children With Febrile Infection-Related Epilepsy Syndrome*, 55 PEDIATRIC NEUROLOGY 22 (2016); and Pediarix Package Insert. Resp't Ex. A at Tabs 1-15.

package insert includes a table showing a higher seizure incidence in patients who received the vaccine over those who received a placebo. *Id.* at 81:23–84:1 (discussing Pet'r Ex. 33 at 6). With regards to the DTaP vaccine, Dr. Steinman testified that the DTaP vaccine's alum adjuvant drives a cytokine response that could become pathogenic. *Id.* at 84:2-85:4; 98:19-99:22. Alternatively, Dr. Steinman theorized that the pertussis toxin in the DTaP vaccine causes a specific kind of enzymatic activity, which in turn "kindle[s]" seizures. *Id.* at 84:22-98:18. And so, Dr. Steinman opined that ADP-ribosylation occurs in the presence of the pertussis toxin, thus confirming that "the pertussis toxin activity is still [occurring] in the acellular vaccines." *Id.* at 95:8-95:22 (discussing Pet'r Ex. 61, S.R. Gomez et al., *ADP-ribosylation Activity in Pertussis Vaccines and its Relationship to the in vivo Histamine-Sensitisation Test*, 25 SCIENCEDIRECT 3311, 3312 (2007)).

Dr. Steinman also opined that the ADP-ribosylation enzymatic process is integral to the triggering of seizures. *Id.* at 94:7-95:1. But, he acknowledged that he could cite no published medical literature in the past 30 years that had expressly hypothesized that ADP-ribosylation causes seizure disorders in the context of vaccines, or that it does so in the timeframe proposed in this case. *Id.* at 118:5-119:19.

During his testimony, Dr. Siegler opined that L.Z. developed afebrile status epilepticus, which is a sign of encephalitis, that resulted in L.Z.'s brain atrophy. *Id.* at 43:24-44:5. Dr. Siegler also testified that the temporal relationship between the vaccines and L.Z.'s condition is the only event he could point to as an etiologic cause, because all other causes were unremarkable. *Id.* at 44:6-44:8.

Dr. Siegler also opined that L.Z.'s April 4, 2014, MRI reading suggested the existence of an inflammatory event occurring in L.Z.'s central nervous system. *Id.* at 36:3-36:21. Dr. Siegler also discussed the stark contrast between L.Z.'s April 2014 MRI and his May 2014 MRI, and he interpreted the decreased brain mass revealed in the May MRI reading as evidence of ongoing diffuse brain atrophy. *Id.* at 39:6-40:10. During cross-examination, Dr. Siegler also testified that he agreed that L.Z. had some developmental issues prior to vaccination, including visual tracking issues, head lag and increased tone. *Id.* at 52:9-54:20. While he acknowledged that some of these symptoms could indicate a pre-existing neurological condition, Dr. Siegler maintained that L.Z.'s pre-vaccination condition was so markedly different from afterward that he could not

associate the former concerns with the latter, more alarming constellation of symptoms. *Id.* at 52:9-54:5.

Lastly, Dr. Zempel testified that L.Z.'s vaccinations did not cause his seizure disorder. *Id.* at 135–213. During his testimony, Dr. Zempel made two overarching contentions: First, that L.Z. likely had some neurologic abnormality before his March 24, 2014, vaccinations. *Id.* at 139:16-146:16. Second, that Dr. Steinman's theory of vaccine causation was unsupported by the medical literature. *Id.* at 158:2-161:10; 164:21-169:14. In this regard, Dr. Zempel testified that there was evidence of possible neurologic abnormalities during L.Z.'s first months of life. *Id.* at 139:16-146:16. Specifically, he noted, among other things, "subtle but persistent concern" from treaters about possible developmental delay, particularly with regard to his head lag, increased tone, poor visual interaction and other motor skills. *Id.* at 139:22-140:9. And so, Dr. Zempel concluded that there was "clear evidence" of neurologic abnormalities before L.Z. received his six-month vaccinations. *Id.* at 144:15-146:13.

Dr. Zempel also testified that the underlying cause of L.Z.'s epilepsy is as yet unknown. *Id.* at 148:4-148:11. In addition, Dr. Zempel testified that he disagreed with the conclusion that vaccines may have played a role in triggering L.Z.'s seizure onset. *Id.* at 158:2-158:13. In this regard, Dr. Zempel testified that he found Dr. Steinman's theory of causation too incoherent to analyze or respond to in full. *Id.* at 168:20-169:5. Dr. Zempel also disputed several of Dr. Steinman's interpretations of medical literature and other evidence. *Id.* at 167:14-167:23. For example, he noted that, while ADP-ribosylation could theoretically play a role in seizure activity, the key medical literature cited by Dr. Steinman for this point said nothing at all about the seizure-inducing capacity of the pertussis toxin. *Id.* Dr. Zempel also took issue with the contention that L.Z.'s medical records established the existence of an inflammatory event at the time of his hospitalization in April 2014. *Id.* at 162:17-163:17. And so, Dr. Zempel characterized L.Z.'s condition as idiopathic in origin. *Id.* at 207.

3. The Special Master's March 21, 2019, Decision

On March 21, 2019, the special master issued a decision denying petitioner's Vaccine Act claim. *See generally* March 21, 2019, Decision. In the March 21, 2019, Decision, the special master determined that: (1) petitioner failed to offer a medically and scientifically reliable theory for how any of the vaccines that L.Z. received on March 24, 2014, could have

caused a seizure disorder and (2) that the record evidence did not support the conclusion that the vaccines L.Z. received on March 24, 2014, likely caused his seizure disorder beginning on April 1, 2014. *Id.* at 22-28. And so, the special master denied petitioner's claim for compensation. *Id.* at 28.

The special master began his analysis of petitioner's claim by discussing the case law pertaining to claims that the pertussis toxin contained in certain vaccines can be the cause of an injury. *Id.* at 22. In this regard, the special master observed that past Vaccine Program decisions have rejected the notion that the residual amounts of inactivated/purified pertussis toxin present in the acellular pertussis vaccine can be considered to cause seizures or encephalopathy to a degree comparable to that of the whole cell version. *Id.*; *see also, e.g., Taylor v. Sec'y of Health & Human Servs.*, 108 Fed. Cl. 807, 820 (2013); *Murphy v. Sec'y of Health & Human Servs*., No. 05-1063V, 2016 WL 3034047, at *12 (Fed. Cl. Spec. Mstr. Apr. 25, 2016), *mot. for review denied*, 128 Fed. Cl. 348 (2016); *James v. Sec'y of Health & Human Servs*., No. 09–284V, 2010 WL 4205699, at *11 (Fed. Cl. Spec. Mstr. Sept. 30, 2010). The special master also observed that the case law reveals older medical literature establishing that the amounts of the toxin contained in versions of the vaccine previously administered are sufficient to be associated with seizures, or other neurologic injuries, but, that medical literature cannot be applied wholesale to the version of the vaccine currently administered. March 21, 2019, Decision at 22; *see also Snyder v. Sec'y of Health & Human Servs.*, No. 07-59V, 2011 WL 3022544, at *30 (Fed. Cl. Spec. Mstr. May 27, 2011) (explaining that applying DTP-related risk data to DTaP is a "problematic" and misleading extrapolation); *see also Sharpe v. Sec'y of Health & Human Servs.*, No. 14-65V, 2018 WL 7625360, at *32 (Fed. Cl. Spec. Mstr. Nov. 5, 2018). And so, the special master noted that claims that the pertussis toxin caused an injury "often founder on a petitioner's inability to establish that the amount of pertussis toxin that may remain in the acellular form of the vaccine is sufficient to provoke neurologic injury." March 21, 2019, Decision at 22 (citing *Murphy*, 2016 WL 3034047, at *12, 33).

Turning to the merits of petitioner's claim, the special master considered whether petitioner had met his burden of proof under prongs one and two of *Althen* and he determined that petitioner had not done so in this case. *Id.* at 22-28. First, with regards to *Althen* prong one, the special master determined that petitioner failed to offer a medically and scientifically reliable theory for how any of the vaccines that L.Z. received could have caused a seizure disorder. *Id.* at

23-25. Specifically, the special master found that "[t]he most credible of [p]etitioner's proffered theories pertained to the DTaP vaccine." *Id.* at 23. But, the special master concluded that this theory "relied on a series of suppositions, not all of which were supported by the filed medical literature or clearly set forth in persuasive expert testimony." *Id.*

In this regard, the special master found that petitioner did not establish what levels of residual pertussis toxin would be sufficient to cause injury, or that the amount of pertussis toxin found in a DTaP vaccine are of that level. *Id.* at 23. Instead, the special master observed that petitioner assumed that any amount would be enough. *Id.* at 23. Specifically, the special master also observed that "[t]he fact that larger amounts [of pertussis toxin] contained in the whole cell version of the vaccine may previously have been determined to be associated with injury does not mean that a version of the vaccine intended to reduce, if not eliminate, that risk is equally problematic." *Id.* He also noted that "articles like Gomez say nothing at all about what levels of residual pertussis toxin are problematic." *Id.* (citing Pet'r Ex. 61 (the purpose of study was to propose more effective and humane test for determining presence of pertussis toxin)).

The special master also found that, while petitioner proposed that the pertussis toxin is associated with an enzymatic process known as ADP-ribosylation, Dr. Steinman conceded during the entitlement hearing that much of the literature offered in support of this contention was outdated. March 21, 2019, Decision at 23 (citing Tr. at 118:5-119:19). In addition, the special master found that the Gomez article "did somewhat support Dr. Steinman's argument," but, there were "limitations to [the article's] findings that reduce its overall probative value." *Id.* at 24 (citing Pet'r Ex. 61 at 3317 (noting that pertussis toxin levels for chemically-detoxified DTaP could *not* be measured well via ADP-ribosylation enzyme activity)). And so, the special master concluded that "Dr. Steinman's theory fails in its most central contention: that 'excessive ADP ribosylation can [. . .] play a neuropathic role leading to seizures and to neuronal death.'"[4] *Id.*

[4] The special master observed that Gomez showed lower ADP-ribosylase enzymatic activity levels in whole cell pertussis than in seven of the eight acellular varieties tested, despite the fact that whole cell pertussis contains more toxin than any detoxified pertussis variety and has been otherwise more credibly associated with neurologic damage than the acellular version. March 21, 2019, Decision at 24 (citing Pet'r Ex. 61 at 3314–15 (finding that "the residual [pertussis toxin] enzymatic activity in [whole cell DTP] was found to be much lower in comparison to DTaP products, with the exception of [one DTaP variety]")).

With regards to the RotaTeq and Hib vaccines that L.Z. received, the special master determined that petitioner's causation theory had even less reliable scientific support. *Id.* In this regard, the special master noted that Dr. Steinman relied almost exclusively on the respective package inserts for these vaccines to substantiate his contention that the RotaTeq or HiB vaccines could have caused L.Z.'s seizures. *Id.*; *see also* Tr. at 81:23–84:1. And so, the special master concluded that the package inserts are generally afforded very little weight in Vaccine Program cases as proof of causation. *Id.* at 25. The special master also found petitioner's claim that the alum adjuvant in DTaP may have played a role in causing L.Z.'s seizures to be unpersuasive, because "[t]his contention was supported with almost no reliable medical literature." *Id.* (citing Pet'r Ex. 46). And so, the special master concluded that petitioner's proffered causation theories were not sufficiently reliable and persuasive to satisfy *Althen* prong one. *Id.*

With regards to *Althen* prong two, the special master determined that petitioner's claim was also unsuccessful because the record evidence does not support the conclusion that the vaccines that L.Z. received on March 24, 2014, caused his seizure disorder beginning eight days later, on April 1, 2014. *Id.* at 25-26. In this regard, the special master found that "there are too many factual gaps in the medical record to discern an association between L.Z.'s vaccinations and his seizures (especially given the sequence of events in this case)." *Id.* at 26. The special master also found that, while seizures can be triggered by a vaccine-induced fever, "L.Z. unquestionably did not experience a fever in conjunction with the vaccinations or the first onset of his seizures over a week later—thereby reducing the likelihood that he was at that time experiencing an underlying inflammatory event." *Id.* He also observed that there was no record evidence suggesting that L.Z. experienced any reaction between the March 24, 2014, vaccinations and his initial seizures. *Id.* And so, the special master found Dr. Zempel's testimony that the difference between L.Z.'s normal MRI reading in April 2014 and abnormal MRI reading in May 2014 was most likely attributable to damage caused by refractory status epilepticus seizure activity—rather than a vaccine-mediated inflammation—to be persuasive. *Id.*

The special master also observed that no other testing from L.Z.'s initial hospitalization confirms petitioner's theory, beyond the evidence of pleocytosis based upon CSF measurements taken after L.Z.'s April 2, 2014, hospitalization. *Id.* In addition, the special master recognized that petitioner offered the testimony of only one treater, Dr. Siegler, who opined that L.Z.'s

seizures were likely vaccine-caused. *Id.* In this regard, the special master noted that "Dr. Siegler was largely a credible witness, who appears to have testified truthfully about his observations in treating L.Z., based on his firsthand knowledge of L.Z.'s medical history." *Id.* at 26-27. But, the special master determined that:

> [S]everal factors lead me to give Dr. Siegler's testimony less weight than what Petitioner might urge. First, no contemporaneous treater other than Dr. Siegler seems to have considered L.Z.'s seizures to have been vaccine-caused. Second, Dr. Siegler's causality views only came into focus in September of 2016—two and a half years after the first onset of L.Z.'s seizures, and after this petition was filed. Only then did Dr. Siegler file a VAERS report. While Dr. Siegler maintained at hearing that in the interim period he had attempted to eliminate other, more likely causes before considering the possibility of vaccine causation, it is well-established in the Vaccine Program that contemporaneous medical records—including treater opinions about possible etiologies—are given more weight than later-in-time statements to the contrary. *See Burns by Burns v. Sec'y of Dep't of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993). Here, those contemporaneous records memorialize Dr. Siegler's view in 2014 that Petitioner's etiology was unlikely to ever be determined.

Id. at 27. And so, the special master concluded that Dr. Siegler's opinion that vaccines caused L.Z.'s seizures loses some of its probative weight when considered in light of the full medical record. *Id.*

Based upon the testimony and the evidentiary record, the special master determined that the eight-day temporal relationship between the March 24, 2014, vaccinations and the onset of L.Z.'s seizure was not, alone, sufficient to demonstrate causation. *Id.* at 28. And so, the special master concluded that the preponderant evidence in this case did not support petitioner's cause of action and he denied entitlement. *Id.*

Petitioner, alleging error, seeks review of the special master's March 21, 2019, Decision.

B. Procedural Background

On April 19, 2019, petitioner filed a motion for review of the special master's March 21, 2019, Decision and a memorandum in support thereof. *See generally* Pet'r Mot. for Rev.; Pet'r Mem. On May 20, 2019, the Secretary filed a response to petitioner's motion for review. *See generally* Resp't Resp. On June 17, 2019, the Court held oral argument on the petitioner's motion for review. *See generally* Tr. on Pet'r Mot. for Review. On July 1, 2019, Judge Charles

F. Lettow recused himself and this case was transferred to Judge Lydia Kay Griggsby. *See* Order of Recusal; Notice of Reassignment.

III. STANDARDS FOR DECISION

A. Vaccine Act Claims

The United States Court of Federal Claims has jurisdiction to review the record of the proceedings before a special master and, upon such review, may:

> (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,
>
> (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
>
> (C) remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa–12(e)(2).

The special master's determinations of law are reviewed *de novo*. *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009). The special master's findings of fact are reviewed for clear error. *Id.* (citation omitted); *see also Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) ("We uphold the special master's findings of fact unless they are arbitrary or capricious."). The special master's discretionary rulings are reviewed for abuse of discretion. *Munn v. Sec'y of Dep't of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

In addition, a special master's findings regarding the probative value of the evidence and the credibility of witnesses will not be disturbed so long as they are "supported by substantial evidence." *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1355 (Fed. Cir. 2010) (citation omitted); *see also Burns by Burns v. Sec'y of Dep't of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is "uniquely within the purview of the special master."). This "level of deference is especially apt in a case in which the medical evidence of causation is in dispute." *Hodges v. Sec'y of Dep't of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). And so, the Court will not substitute its judgment for that of the

special master, "if the special master has considered all relevant factors, and has made no clear error of judgment." *Lonergan v. Sec'y of Dep't of Health & Human Servs.*, 27 Fed. Cl. 579, 580 (1993).

Under the Vaccine Act, the Court must award compensation if a petitioner proves, by a preponderance of the evidence, all of the elements set forth in 42 U.S.C. § 300aa–13(a)(1). A petitioner can recover either by proving an injury listed on the Vaccine Injury Table (the "Table"), or by proving causation-in-fact. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C)(i)-(ii); *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). And so, to receive compensation under the National Vaccine Injury Compensation Program, a petitioner must prove either that: (1) the petitioner suffered a "Table Injury" that corresponds to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) the petitioner's illnesses were actually caused by a vaccine. *See* 42 U.S.C. §§ 300aa–11(c)(1)(C)(i)-(ii), 300aa–14(a); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006).

In addition, in Table and non-Table cases, a petitioner bears "a preponderance of the evidence" burden of proof. 42 U.S.C. § 300aa–13(a)(1)(A); *Althen*, 418 F.3d at 1278 (citing *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)). And so, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the [judge] of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2 (brackets existing) (citations omitted); *see also Snowbank Enters. v. United States*, 6 Cl. Ct. 476, 486 (1984) (finding that mere conjecture or speculation is insufficient under a preponderance standard).

To establish a prima facie case, a petitioner must "prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface*, 165 F.3d at 1352. In addition, petitioner must prove by a preponderance of the evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and

injury." *Althen*, 418 F.3d at 1278. But, medical or scientific certainty is not required. *Knudsen by Knudsen v. Sec'y of Dep't of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994).

The Federal Circuit addressed the three elements to prove causation-in-fact in *Althen*. *Althen*, 418 F.3d at 1278. The Federal Circuit has also held that all three of these elements "must cumulatively show that the vaccination was a 'but-for' cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm." *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006).

In addition, if a petitioner establishes a prima facie case, the burden shifts to the respondent to show, by a preponderance of the evidence, that the injury was caused by a factor unrelated to the vaccine. *See* 42 U.S.C. § 300aa–13(a)(1)(B); *Shalala v. Whitecotton*, 514 U.S. 268, 270-71 (1995). But, regardless of whether the burden of proof shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a *prima facie* case. *See Stone v. Sec'y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) ("[E]vidence of other possible sources of injury can be relevant not only to the 'factors unrelated' defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question."); *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1353 (Fed. Cir. 2008) ("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case[-]in-chief.").

IV. LEGAL ANALYSIS

Petitioner raises three objections to the special master's March 21, 2019, Decision in the motion for review. *See generally* Pet'r Mot. First, petitioner argues that the special master committed legal error by conducting the *Althen* analysis with a different theory of causation than the one presented by petitioner. Pet'r Mot. at 1. Second, petitioner argues that the special master committed legal error by giving insufficient deference to the testimony of L.Z.'s treating neurologist. *Id.* at 2. Lastly, petitioner argues that the special master committed legal error by substituting his own medical judgment for the expert testimony. *Id.* And so, petitioner requests that the Court set aside the March 21, 2019, Decision and remand this matter to the special master for further proceedings. *Id.*

The Secretary counters in his response that the special master correctly determined that petitioner was not entitled to compensation under the Vaccine Act, because petitioner failed to present a persuasive medical theory causally connecting L.Z.'s vaccinations to his injury. Resp't Resp. at 7-11. The Secretary also argues that the special master did not err in weighing the testimony of L.Z.'s treating neurologist, because Dr. Siegler was the only contemporaneous treater to link L.Z.'s vaccinations to his injury and the special master has discretion to weigh his testimony in light of the entire medical record. *Id.* at 11-16. And so, the Secretary requests that the Court deny petitioner's motion for review and sustain the decision of the special master. *Id.* at 16-17.

For the reasons discussed below, the evidentiary record in this matter shows that the special master did not abuse his discretion, or act contrary to law, in reaching the decision to deny petitioner's Vaccine Act claim. And so, the Court: (1) **DENIES** petitioner's motion for review and (2) **SUSTAINS** the decision of the special master.

A. The Special Master Properly Analyzed Petitioner's Theory Of Causation

As an initial matter, the evidentiary record does not support petitioner's claim that the special master committed legal error by conducting an analysis under *Althen* prong one with a different theory of causation than the theory presented by petitioner. The Court reviews the special master's determinations of law *de novo*. *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1373 (Fed. Cir. 2009).

1. The Special Master Correctly Stated Petitioner's Theory Of Causation

In the motion for review, petitioner argues that the special master "fundamentally misunderstood the ADP-ribosylation theory as set forth in the expert reports and testimony of Dr. Steinman, [p]etitioner's expert neurologist." Pet'r Mem. at 7. But, as discussed below, a review of the record evidence makes clear that the special master correctly understood and analyzed the theory of causation put forth by petitioner in this case. *See generally id.*; Pet'r Pet.; March 21, 2019, Decision.

In the March 21, 2019, Decision, the special master correctly observed that petitioner's medical expert, Dr. Steinman, opined that the DTaP vaccine could cause seizures in two different ways. March 21, 2019, Decision at 10. Specifically relevant here, the special master observed

that Dr. Steinman "theorized that the pertussis toxin in the vaccine causes a specific kind of enzymatic activity, which in turn 'kindle[s]' seizures." *Id.* (alteration in the original). And so, the special master understood petitioner's medical theory to be that "small amounts of the pertussis toxin remaining in the DTaP vaccine could cause seizures." *Id.* at 23 (citing Pet'r Ex. 26 at 6-7); *see also* Tr. at 87:16-89:23.

The record evidence also shows that Dr. Steinman advanced this precise theory of causation during his entitlement hearing testimony. Dr. Steinman testified that "it's the toxin [in the acellular version of the DTaP vaccine] that provokes the protective immune response . . . ." Tr. at 89:10-89:16; *see also* Pet'r Ex. 26 at 6-7. Dr. Steinman also testified that ADP-ribosylation can trigger seizures and that he believed there is sufficient residual pertussis toxin in the DTaP vaccine to incite an ADP-ribosylation reaction. Tr. at 93:3-93:24. And so, as the special master correctly stated in the March 21, 2019, Decision, Dr. Steinman opined that L.Z.'s seizures resulted from an inflammatory reaction caused by the pertussis toxin in the DTaP vaccine and the special master correctly stated this theory in the March 21, 2019, Decision. *See id.* at 119:8-119:12; *see also* March 21, 2019, Decision at 13.

2. The Special Master Reasonably Concluded That Petitioner Failed To Satisfy *Althen* Prong One

The record evidence also shows that the special master reasonably concluded that petitioner failed to meet his burden of proof under *Althen* prong one with regards to his theory of causation. In the March 21, 2019, Decision, the special master determined that petitioner had not met his burden under prong one of *Althen*, because petitioner failed to offer a medically and scientifically reliable theory for how any of the vaccines that L.Z. received on March 24, 2014, could have caused a seizure disorder. March 21, 2019, Decision at 23-25. With regards to the DTaP vaccine in particular, the special master determined that petitioner's theory "relied on a series of suppositions, not all of which were supported by the filed medical literature or clearly set forth in persuasive expert testimony." *Id.* at 23. In this regard, the special master found that petitioner did not establish what level of residual pertussis toxin would be sufficient to cause injury, or that the amount of pertussis toxin found in the DTaP vaccine is of that level. *Id.*

The special master also found that, while the Gomez article—upon which petitioner relied—"did somewhat support Dr. Steinman's argument, . . . there were limitations to its findings that reduce its overall probative value" in this case. *Id.* at 24 (citing Pet'r Ex. 61 at 3317

(noting that pertussis toxin levels for chemically-detoxified DTaP could not be measured well via ADP-ribosylation enzyme activity)).[5] Notably, the special master found that "articles like Gomez say nothing at all about what levels of residual pertussis toxin are problematic." *Id.* at 23 (citing Pet'r Ex. 61 (the purpose of study was to propose more effective and humane test for determining presence of pertussis toxin)).

The special master also correctly observed that Dr. Steinman conceded during the entitlement hearing that much of the medical literature offered in support of petitioner's theory that the pertussis toxin is associated with ADP-ribosylation was outdated.[6] *Id.* (citing Tr. at 118:5-119:19). And so, the record evidence shows that the special master reasonably concluded that "Dr. Steinman's theory fails in its most central contention: that 'excessive ADP ribosylation can [. . .] play a neuropathic role leading to seizures and to neuronal death,'" based upon the evidentiary record, and in particular, the absence of support for petitioner's theory of causation in the medical literature. *Id.* at 24.

3. Petitioner's Remaining Objections Are Unsubstantiated

Petitioner's remaining objections to the special master's analysis under *Althen* prong one are also unconvincing. Petitioner argues that the special master erred in considering the level of pertussis toxin needed to trigger a seizure because his theory of causation is not based upon a dose-dependent response of the pertussis toxin in the DTaP vaccine. Pet'r Mem. at 7. It is true that petitioner's theory of causation is not dependent upon a specific amount of residual pertussis toxin contained in the DTaP vaccine. But, the record evidence also shows that petitioner failed to put forward evidence to show that *any* residual amount of this toxin could cause seizures. *See* March 21, 2019, Decision at 23; *see generally* Pet'r Exs. Indeed, as the special master observed in the March 21, 2019, Decision, the fact that the larger amounts of residual pertussis toxin contained in the whole cellular version of the DTaP vaccine have been associated with seizures

[5] The special master correctly found that the Gomez article did not stand for the proposition that excessive ADP-ribosylation can play a neuropathic role leading to seizures. March 21, 2019, Decision at 24 (citing Pet'r Ex. 61 at 3317 (noting that pertussis toxin levels for chemically-detoxified DTaP could *not* be measured well via ADP-ribosylation enzyme activity)).

[6] The special master also found that Dr. Steinman "did not demonstrate that any research he performed in the past relating to pertussis toxin and the means by which it might be theoretically understood to cause seizures has been confirmed or corroborated in the past ten years." March 21, 2019, Decision at 24.

does not necessarily mean that the acellular version of this vaccine—which has been designed to reduce such risks—would cause seizures. March 21, 2019, Decision at 23. Given this—and the absence of evidence to support petitioner's theory that any residual amount of pertussis toxin in the DTaP vaccine could have caused L.Z.'s injury—the special master reasonably considered whether there was any evidence to show what amount of pertussis toxin is sufficient to cause an injury in this case.[7] *Id.*

B. The Special Master Reasonably Weighed The Testimony Of Dr. Siegler

Petitioner's objection that the special master committed legal error by giving insufficient deference to the testimony of L.Z.'s treating neurologist, Dr. Siegler, is also unsubstantiated. The Court will not disturb the special master's findings regarding the probative value of evidence and the credibility of witnesses so long as they are "supported by substantial evidence." *Doe*, 601 F.3d at 1355 (citation omitted); *see also Burns*, 3 F.3d at 417 (holding that the decision of whether to accord greater weight to contemporaneous medical records or later given testimony is "uniquely within the purview of the special master.").[8]

Petitioner argues that the special master improperly minimized the weight of Dr. Siegler's testimony by, (1) stating that "no contemporaneous treater other than Dr. Siegler seems to have considered L.Z.'s seizures to have been vaccine caused" and (2) criticizing Dr. Siegler's reliance upon the temporal nexus between vaccination and the onset of L.Z.'s seizures. Pet'r Mem. at 14, 16; *see also* March 21, 2019, Decision at 27-28. But, the March 21, 2019, Decision

[7] For similar reasons, petitioner also has not shown that the special master erred by considering the differences between the amount of residual pertussis toxin found in the acellular and whole-cellular DTaP vaccines when analyzing this claim. Pet'r Mem. at 10-11. As discussed above, the special master found gaps in petitioner's theory of causation, because petitioner failed to put forward evidence to show that any residual amount of the pertussis toxin contained in the acellular DTaP vaccine could cause seizures. March 21, 2019, Decision at 23. The record evidence also shows that the special master did not conflate the terms pertussis toxin and ADP-ribosylation, as petitioner suggests. Pet'r Mem. at 10-11. The special master's statement in the March 21, 2019, Decision that the Gomez article stands for the proposition that there was lower ADP-ribosylation enzymatic activity in the whole-cellular DTaP vaccine than in the acellular DTaP vaccine is consistent with the findings in the Gomez article. *See* Pet'r Ex. 61.

[8] The Federal Circuit has held that "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury." *Andreu*, 569 F.3d at 1375 (quoting *Capizzano*, 440 F.3d at 1326); *see also Zatuchni v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 612, 623 (Fed. Cl. 2006) (relying heavily on the testimony of treating physicians in concluding that Vaccine Act causation had been established).

and the record evidence make clear that the special master appropriately weighed Dr. Siegler's testimony in this case for three reasons.

First, the special master's finding that Dr. Siegler's testimony had less probative value because no other contemporaneous treater of L.Z. considered L.Z.'s seizures to have been vaccine-caused is reasonable and supported by the evidentiary record. In the March 21, 2019, Decision, the special master observed that "Dr. Siegler was largely a credible witness, who appears to have testified truthfully about his observations in treating L.Z., based on his firsthand knowledge of L.Z.'s medical history." March 21, 2019, Decision at 26-27. But, the special master correctly determined that "no contemporaneous treater *other* than Dr. Siegler seems to have considered L.Z.'s seizures to have been vaccine-caused." *Id.* at 27 (emphasis original). Petitioner does not dispute that Dr. Siegler is the only treater who has connected L.Z.'s seizures to a vaccine. *See* Pet'r Mem. at 15. And so, the special master's finding that Dr. Siegler's testimony lost some of its probative weight because no other contemporaneous treater linked L.Z.'s seizures to the vaccines is reasonable and supported by the evidentiary record in this case.

The special master's finding that Dr. Siegler's testimony had less probative value, because Dr. Siegler's contemporaneous medical notes reflect that he believed that L.Z.'s etiology was not likely to ever be determined, is similarly supported by the substantial evidence. In the March 21, 2019, Decision, the special master correctly determined that Dr. Siegler's contemporaneous medical notes state that he believed that L.Z.'s diagnosis was unlikely to ever be determined. March 21, 2019, Decision at 27; *see also* Pet'r Ex. 11, Part 1, at 38 ("I reviewed the expectation that [L.Z.'s] diagnosis will not be determined . . . ."). And so, the special master appropriately afforded these contemporaneous medical notes regarding L.Z.'s diagnosis more weight than Dr. Siegler's testimony during the entitlement hearing. *Burns*, 3 F.3d at 417 (stating that contemporaneous medical records—including treater opinions about possible etiologies—are given more weight than later-in-time statements to the contrary).

The special master's finding that Dr. Siegler's testimony was less probative because Dr. Siegler first identified a link between L.Z.'s seizures and the vaccines after this case was filed is similarly supported by the substantial evidence. In the March 21, 2019, Decision, the special master observed that "Dr. Siegler's causality views only came into focus in September of 2016—two and a half years after the first onset of L.Z.'s seizures, and after this petition was filed."

March 21, 2019, Decision at 27. As the special master correctly observed, Dr. Siegler filed a VAERS report linking the vaccines to L.Z.'s injuries more than two years after the onset of L.Z.'s symptoms. *Id.*; *see also* Pet'r Ex. 17. Given this, the special master reasonably concluded that Dr. Siegler's contemporaneous medical notes stating that L.Z.'s etiology was unlikely to ever be determined should be "given more weight than later-in-time statements to the contrary" during the entitlement hearing. March 21, 2019, Decision at 27; Tr. at 48:10-49:15; *see also Burns*, 3 F.3d at 417.

Indeed, while petitioner contends that the special master improperly criticized Dr. Siegler for relying upon the eight-day temporal proximity between L.Z.'s vaccination and the onset of symptoms to establish causation in this case, the record evidence shows that the special master correctly determined that such a temporal relationship, alone, is not a sufficient basis upon which to find causation. March 21, 2019, Decision at 28; *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1323 (Fed. Cir. 2010); *see also* Pet'r Mem. at 16. And so, the substantial evidence in the record makes clear that the special master had several sound reasons for affording less weight to Dr. Siegler's testimony and that the special master reasonably concluded that petitioner had not established causation in this case.[9]

C. The Special Master Did Not Substitute His Medical Judgment For The Expert Testimony

Petitioner's third objection—that the special master improperly substituted his medical judgment for the testimony of petitioner's expert witnesses—is also unsubstantiated by the record evidence. Pet'r Mem. at 16-18.

As discussed above, the special master determined in the March 21, 2019, Decision, that the record evidence did not support the conclusion of petitioner's medical experts—that the vaccines that L.Z. received on March 24, 2014, likely caused his seizure disorder. March 21, 2019, Decision at 25-26. Specifically, the special master found that "there are too many factual

[9] The record evidence also makes clear that the special master appropriately weighed the testimony of Dr. Zempel. As the special master observed in the March 21, 2019, Decision, Dr. Zempel's work as a pediatric neurologist is focused upon epilepsy. March 21, 2019, Decision at 13; *see also* Resp't Ex. A at 1. Dr. Zempel's expert opinion that there was "clear evidence" of neurologic abnormalities before L.Z. received his six-month vaccinations is also supported by the medical record. Tr. at 144:15-146:13; Pet'r Ex. 3 at 62.

gaps in the medical record to discern an association between L.Z.'s vaccinations and his seizures (especially given the sequence of events in this case)." *Id.* at 26. The special master also found that, while seizures can be triggered by a vaccine-induced fever, "L.Z. unquestionably did not experience a fever in conjunction with the vaccinations or the first onset of his seizures over a week later—thereby reducing the likelihood that [L.Z.] was at that time experiencing an underlying inflammatory event." *Id.* And so, the special master concluded that there was no record evidence suggesting that L.Z. experienced any reaction between the March 24, 2014, vaccinations and his initial seizures. *Id.*

The special master did not err in reaching this conclusion. The special master's finding that L.Z. did not experience a fever in connection with the March 24, 2014, vaccinations is supported by the record evidence. Notably, Dr. Siegler's narrative report states that "[L.Z.'s] dad, Nicholas, reports no fever at the time or soon after seizures began." Pet'r Ex. 24 at 14; *see also* Pet'r Ex. 22, Part 10, at 2522 (showing that, on April 1, 2014, L.Z. experienced a seizure, but showed no signs of a fever). Petitioner also argues without persuasion that the special master erred in finding that "there is no record evidence suggesting that L.Z. experienced any reaction at all between the March 24th vaccinations and his initial seizures [on April 1, 2014]." Pet'r Mem. at 17; *see also* March 21, 2019, Decision at 26. But, again, the special master's finding accurately describes the evidence in the medical record showing that L.Z.'s "most striking neurologic symptoms began 7 days following [his] 6 months vaccinations [on March 24, 2014] . . . ." Pet'r Ex. 24 at 14; *see also* Pet'r Ex. 26 at 4 (Dr. Steinman stated that "[s]eizures began somewhere 7 to 8 days after the March 24 immunizations . . . .").

The special master's determination that L.Z.'s pleocytosis test did not establish that the vaccines caused neuro-inflammation is also consistent with the evidentiary record. Pet'r Mem. at 18; *see also* March 21, 2019, Decision at 26. As the special master correctly observed in the March 21, 2019, Decision, the record evidence shows that L.Z.'s pleocytosis test occurred after the onset of his seizures and that the MRI performed after the onset of L.Z.'s seizures was normal. *See* Pet'r Ex. 24 at 14 (stating that the MRI performed on April 4, 2014, after L.Z.'s first seizure, was normal despite CSF pleocytosis). And so, the record evidence makes clear that the special master did not substitute his judgment for that of the medical experts, but, rather, the special master based his findings and conclusion in this case upon the totality of the medical record. The Court will not disturb the special master's findings.

V. CONCLUSION

In sum, the evidentiary record in this matter shows that the special master correctly understood petitioner's theory of causation, afforded proper weight to the testimony of Dr. Siegler and based his conclusion that petitioner had not established an entitlement to recover compensation under the Vaccine Act in this case upon the entire medical record. And so, for the forgoing reasons, the Court:

(1) **DENIES** petitioner's motion for review; and

(2) **SUSTAINS** the decision of the special master.

The Clerk shall enter judgment accordingly.

Some of the information contained in this Memorandum Opinion and Order may be considered privileged, confidential or sensitive personally-identifiable information that should be protected from disclosure. And so, this Memorandum Opinion and Order shall be **FILED UNDER SEAL**. The parties shall review the Memorandum Opinion and Order to determine whether, in their view, any information should be redacted prior to publication. The parties shall also **FILE**, by **October 25, 2019**, a joint status report identifying the information, if any, that they contend should be redacted, together with an explanation of the basis for each proposed redaction.

IT IS SO ORDERED.

s/Lydia Kay Griggsby
LYDIA KAY GRIGGSBY
Judge